

# Study of promising cancer therapy halted due to deaths

July 8 2016, by Matthew Perrone

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A study of an experimental treatment for leukemia was abruptly halted this week following two patient deaths, raising questions about a closely-watched approach to cancer that involves reprogramming cells to seek and destroy the disease.

The Food and Drug Administration suspended the Juno Therapeutics trial Wednesday, after the company reported that two patients on its most advanced treatment died from swelling of the brain. A similar death was reported in May though both the FDA and Juno concluded there were "compounding factors," company executives said in a Thursday conference call.

Seattle-based Juno blamed the two recent deaths on the addition of a second chemotherapy drug to its pre-treatment regimen, rather than on the company's new therapy. The FDA is expected to let the study of the drug continue without the additional chemotherapy drug.

Juno's initial studies used only one chemotherapy drug to prime the immune system to work with the experimental therapy. But after adding a second drug, fludarabine, doctors saw an increase in "severe neurotoxicity," said CEO Hans Bishop.

"The last week has been difficult and humbling for everyone involved, in particular, of course, the physicians and the patients' families," said Bishop.

Experts said the researchers are taking the right approach by stopping the study and proceeding with caution. But they added that such setbacks are part of the research process.

"This sort of thing is incredibly common in new drug development. It's unfortunate, but I don't know how you avoid it," said Dr. Otis Brawley, chief medical officer for the American Cancer Society.

Juno's approach is part of a promising, but still unproven, approach that reengineers patients' immune systems to attack cancer. The company filters patients' blood to remove white blood cells called T-cells and genetically alters them in the lab so they can target cancer cells. They then return the modified cells to the patient.

One of study's researchers says that more than 300 patients have been treated with similar therapies in the U.S., without reports of brain swelling.

"These are relatively rare events, so I don't think it changes the fundamental promise or the long-term plan here," said Dr. Jae Park of Memorial Sloan Kettering Cancer Center in New York, who is one of several physicians conducting the trial.

The company's therapy, known only as JCAR015, is in mid-stage testing, a make-or-break phase of development that usually focuses on effectiveness. Twenty patients are now enrolled in the trial and the company aims to eventually enroll 90 patients.

The company said it will seek FDA permission this week to continue the study without fludarabine. For now, the trial is on hold until the FDA signs off on new testing protocols, patient disclosure forms and other elements of the trial. Juno said that the FDA has agreed to review those materials on an accelerated timetable.

Juno is studying several similar gene-altering immunotherapies for various forms of leukemia and expects its first approval in early 2018. Other companies in the field include Novartis and Kite Pharma.

Juno shares plunged more than 30 percent in trading Friday to close at \$27.81.

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